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|---|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.   | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/564,712  | 01/12/2006    | Werner Baschong      | HU/15-22918/A/PCT   | 9870             |
| 324   | 7590          | 03/20/2008           | EXAMINER            |                  |
| JoAnn Villamizar<br>Ciba Corporation/Patent Department<br>540 White Plains Road<br>P.O. Box 2005<br>Tarrytown, NY 10591 |               |                      | WESTERBERG, NISSA M |                  |
| ART UNIT  | PAPER NUMBER  |                      | 1618                |                  |
| MAIL DATE   | DELIVERY MODE |                      |                     |                  |
| 03/20/2008  | PAPER         |                      |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |  |                         |
|------------------------------|--|-------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b>                 | <b>Applicant(s)</b>     |
|                              | 10/564,712                             | BASCHONG ET AL.         |
|                              | <b>Examiner</b><br>Nissa M. Westerberg | <b>Art Unit</b><br>1618 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

1) Responsive to communication(s) filed on 22 January 2008.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

4) Claim(s) 1-8,11,14 and 15 is/are pending in the application.

4a) Of the above claim(s) 7, 15 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1- 6, 8, 11 and 14 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### **Priority under 35 U.S.C. § 119**

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### **Attachment(s)**

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/96/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

Applicants' arguments and amendments, filed January 22, 2008, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

***Specification***

1. The specification was objected to because of the use of trademarks and the presence of the term "L\*" with no explanation of the term. The trademarks in the specification have been corrected. The Examiner thanks Applicant for the explanation of the term L\* and providing references in regards to this term. The objection to the specification is WITHDRAWN.

***Claim Rejections - 35 USC § 103***

2. Claims 1 – 6, 8 – 12 and 14 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hague (WO 01/70189) in view of Sakoda et al (WO 98/17247) and Ashby et al. (Regul Toxicol Pharmacol 2001). Due to the cancellation of claims 9, 10 and 12, this rejection is currently applied to claims 1 – 6, 8, 11 and 14.

Applicant traverses this rejection on the basis of surprising results provided in the working examples and the references are not properly combination because of a lack of teaching, suggestion or inference in the art or the generally available knowledge of a person of ordinary skill in the art to arrive at a method of lightening the skin with a composition comprising a halogenated hydroxydiphenyl ether (component (a)), a skin lightening substance (component (b)) and a triazine UV absorber (component (c)).

In regards to the surprising results, there does not appear to be a working example in which a composition comprising the elected components of formula 3 or triclosan for component (a), kojic acid as component (b) and the sunscreen of formula (5e) or TINASORB B® for component (c) is tested. The compositions tested on subjects in example 6 contain component (a) but do not contain components (b) or (c). Therefore, the Examiner was unable to find any results for the compositions to determine whether or not those results were unexpected. If Applicant is in disagreement with the Examiner regarding the presence of results for the elected composition, Applicant is respectfully requested to point to page and line number wherein those results may be found for the instant invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in

the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In this case, Hague and Sakoda et al. both teach compositions that are useful in methods of lightening the color of the skin. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) **MPEP 2144.06**. The resulting composition useful for lightening skin, and due to the presence of an anti-microbial agent is also useful in a method for the simultaneous antimicrobial treatment of the skin, comprises triclosan, kojic acid and sunscreen.

The use of triazine sunscreens such as TINASORB S® is not disclosed by either Hague or Sakoda et al. However, the use of sunscreens in compositions useful in methods of lightening the skin is disclosed. Given the improved properties of the TINASORB S® sunscreen taught by Ashby et al., it would have been obvious to one of ordinary skill in the art to replace the sunscreens taught by Hague or Sakoda et al. with the functional equivalent triazine sunscreen with improved properties taught by Ashby et al. The deficiency of the secondary reference Ashby et al. as to applications for the sunscreens is not a relevant factor in an obviousness analysis.

Applicant had amended independent claim 1 to include weight percent requirements for each component. Hague discloses about 0.01 to about 5% by weight of the anti-microbial agent (component (a)) and about 0.1 to about 30% by weight of a

sunscreen agent (component (c)) ((p 3, ln 1 – 9). Sakoda et al. discloses the amount of kojic acid typically present in these compositions to be about 0.5% to about 3% by weight of the composition (p 2, ln 28 – 34).

Therefore the rejection of claims 1 – 6, 8, 11 and 14 by Hague in view of Sakoda et al. and Ashby et al. in MAINTAINED.

***New Claim Rejections - 35 USC § 112 – 1<sup>st</sup> Paragraph***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 – 6, 8, 11 and 14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has amended this claim to recite the presence of 0.05 to 1% by weight of the composition for component (b). In original claim 25, cited as supporting this amendment, the range for component (b) is 0 to 10% by weight. In the specification on p 35 for the presence of 0.05% by weight of component (b) is recited but the Examiner was unable to find support for the other endpoint, namely a concentration of 1% of component (b). If Applicant is in disagreement with the Examiner regarding support for the amended endpoint of the

range in claim 1 for component (b), Applicant is respectfully requested to point to page and line number wherein support may be found for the instant invention.

***Conclusion***

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/  
Supervisory Patent Examiner, Art Unit 1618

NMW